

DOCKET NO. MUR-037-USA-P

REMARKS

Pursuant to the discussions held during the telephone interviews with Examiner Bockelman on August 5 and 16, 2005, claims 1-4 have been cancelled, and claims 5-7 have been amended to more definitely set forth the invention and obviate the rejections. Support for the amendment of claims 5-7 can be found in the Specification on page 10, lines 9-16. In addition, new claims 10-14 have been presented. Support for new claims 10-14 can be found in the Specification on pages 3, lines 22-27, page 4, lines 21-22, page 9, lines 14, to page 10, line 8. The present amendment is deemed not to introduce new matter. Claims 5-14 are now in the application.

Reconsideration is respectfully requested of the rejection of Claims 5 and 6 under 35 U.S.C. § 102(b) as being anticipated by Hollingsworth or Higo, et al.

The Hollingsworth reference discloses an iontophoresis device by which obtundents or local anesthetics can be readily applied electrically to prevent infliction of pain during dental operations. There is, however, no disclosure whatever in Hollingsworth of an iontophoresis system for non-invasively taking a physiological substance out of a body as called for in the claims herein. Further, there is clearly no recitation in Hollingsworth of having a first electrode structure having a physiological extraction pad thereon, said first electrode structure affixed to a first fixing member, and a second electrode structure affixed to a second fixing member, said second fixing member hingedly engaged with said first fixing member at a hinge connection so as to form a cross shape, as is now claimed herein in amended claim 5.

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The Higo, et al. reference discloses an iontophoresis device which can be applied to mucous membranes and oral mucous membranes to efficiently administer medicines to the body. However, Higo, et al., like Hollingsworth, fail to disclose an iontophoresis system for non-invasively taking a physiological substance out of a body. Moreover, as with the Hollingsworth reference discussed above, Higo, et al. fail to disclose a first electrode structure having a physiological extraction pad thereon, said first electrode structure affixed to a first fixing member, and a second electrode structure affixed to a second fixing member, said second fixing member hingedly engaged with said first fixing member at a hinge connection *so as to form a cross shape*, for non-invasively extracting physiological substances from the body, as now claimed in amended claim 5. Rather, that teaching comes only from the present invention, and constitutes an important element or aspect thereof.

In view of the discussions with Examiner Bockelman during the interview of August 16, 2005, amendments to claim 5 herein, and the subsequent deficiencies of the cited Hollingsworth and Higo, et al. references as mentioned above, it is believed that both of these two cited references now fail to anticipate the claims herein. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1, 3-4, and 7-8 under 35 U.S.C. § 103(a) as being unpatentable over Tapper (USPN 6,059,736) in view of Glikfeld, et al. (USPN 5,279,543).

Claims 1 and 3-4 have been cancelled herein. Thus, this rejection now applies only to existing claims 7-8, both of which now depend upon amended claim 5 herein.

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The Tapper reference discloses a method and apparatus for non-invasively withdrawing and accurately evaluating analytes using a high-voltage system. For example, Tapper discloses in column 13, lines 5-27, using voltages of 60 – 70 volts DC to an active negative electrode 64 drawing up to 3 millamps with no injury.

In contradistinction, the present invention is concerned with an iontophoresis system for non-invasively withdrawing a physiological substance from the body using a low voltage. In this regard, Claims 1 and 7 have been amended to spell out specifically that a voltage of 10 volts or less is used for a period of from about 30 seconds to 20 minutes. The use of such low voltages and low current densities is described in the Specification herein on page 10, lines 9-22, wherein it is disclosed that a voltage of 10 volts or less can be advantageously used.

The Tapper reference nowhere discloses the use of electrical energy of 10 volts or less in carrying out a non-invasive iontophoresis to extract physiological substance from a body. Moreover, as the Examiner has apparently recognized, the cited secondary reference of Glikfeld, et al. merely discloses the use of voltages lower than 10 volts, BUT discloses a structure in no way similar to that claimed herein. In addition, as mentioned above, the instant rejection now applies only to claims 7 and 8, both of which now depend upon amended claim 5.

It is believed, in view of the amendments to claims 5, 7 and 8, and in view of the deficiencies of the cited references described above, that Tapper, either alone or in combination with Glikfeld, et al., in no way renders unpatentably obvious the subject matter now called for in the claims herein. Therefore, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

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Reconsideration is respectfully requested of the rejection of Claims 2 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Tapper (USPN 6,059,736) in view of Glikfeld, et al. USPN 5,279,543), and further in view of Cormier, et al. (USPN 6,219,574)

The Tapper reference and the Glikfeld, et al. reference is discussed above.

The Cormier, et al. reference, the Examiner's secondary reference, fails to cure the deficiencies of the Tapper reference since this combination of references fails to disclose the low voltage system having electrical energy of 10 volts or less for non-invasively removing a physiological substance out of a living body *by using the iontophoresis system as claimed in claim 5 herein.*

In particular, the method of the present invention constitutes an improvement in the art by having the characteristic of non-invasively extracting via a mucous membrane a physiological substance from a living body so as to shorten the detection time, compared with the prior art in which the physiologically active substance has been extracted from skin. This process is achieved using an iontophoresis system for non-invasively extracting a physiological substance out of a living body comprising:

a first electrode structure having a physiological extraction pad thereon, said first electrode structure affixed to a first fixing member,

a second electrode structure affixed to a second fixing member, said second fixing member hingedly engaged with said first fixing member at a hinge connection so as to form a cross shape,

a spring member in attachment to the first fixing member and the second fixing member, on one side of the hinge connection, so as to bias the first electrode structure and the second electrode structure together, and

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a power supply device connected to the electrode structures.

It is believed that the process now called for in the claims herein constitutes a significant advance over the prior art of record, and that the claimed method, using the claimed iontophoresis system of claim 5, is NOT obvious in view of the cited combination of references. Consequently, it is believed that the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance and early action and allowance thereof is accordingly respectfully requested. In the event that there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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Date: August 17, 2005

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